<u>EBMT</u> Annual report 2020



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Sofie Terwel Regulations & GoCART Project Coordinator Netherlands

Cellular therapies manufactured from cells of haematopoietic origin such as CAR Tcell therapies provide a revolutionary treatment for patients suffering from haematological diseases. Nonetheless, there are considerable challenges in the implementation of these therapies in this rapidly evolving field. These include but are not limited to the complexity of the supply chains for these living drugs and the management of side-effects, requiring centre qualification as well as additional and ongoing education of health care professionals; the long term follow up of patients treated with therapies with a curative intent; the myriad of regulatory requirements at European Union and local level; and reimbursement of the treatments by budgetconstrained authorities.

The COVID-19 pandemic has shown us that collaboration is key to combat complex diseases and saving lives. Likewise, the challenges in the field of cellular therapies require us to collaborate across stakeholders. EBMT is proud to have taken the first steps towards realising a multi-stakeholder Coalition. GoCART aims to promote patient access to novel cellular therapies manufactured from cells and tissues of hematopoietic origin and to contribute to health and well-being through innovation by multi-stakeholder collaboration on clinical data, standards of care, education and policy.

EHA is the cofounder of the coalition and other stakeholders include patient representatives, health care professionals, pharmaceutical companies, regulators, Health Technology Assessment (HTA) bodies and reimbursement agencies, and medical organisations both at European and national level.

Main achievements of 2020:

- Launch of the multi-stakeholder coalition.
- More than 15 interviews with representatives of different stakeholder groups were held to get a better understanding of the interests, expectations and potential barriers for participation. The feedback received resulted in a revision of the Governance Charter, which will be further reviewed and finalised in 2021.
- Work package 1 on data harmonisation invited GoCART coalition stakeholders to participate in the review of the EBMT Cellular Therapy form to ensure the form is up-to-date with the latest developments in the field
- Work package 2 on standards of care, launched a committee working on the harmonisation of existing centre qualification schemes to reduce inspection burden for centres.

For 2021 the main goals are to:

• Consolidate the activities of work package 1 and 2 and to start-up activities for the other work packages on: education, health technology assessments, scientific excellence, and policy and advocacy.

- Consolidate GoCART Coalition governance structure and set-up Coalition management processes
- Expand GoCART Coalition network and align it with other initiatives

If you want to get involved in the GoCART activities and work with different stakeholders to maximise the potential of cellular therapies, please send an e-mail to <u>GoCART@ebmt.org</u>